

Practitioner's Docket No. 18326.0000

**IN THE UNITED STATES DESIGNATED OFFICE (DO/US)**

PCT/DE00/01243 18 April 2000 22 April 1999  
 INTERNATIONAL APPLICATION NO. INTERNATIONAL FILING DATE PRIORITY DATE CLAIMED  
Apparatus for Recording a Thermo-optical Image of the Female Breast  
 TITLE OF INVENTION  
Heinrich Wehberg  
 APPLICANT(S) FOR DO/US

**Box PCT**  
**Assistant Commissioner for Patents**  
**Washington, D.C. 20231**

**ATTENTION: DO/US**

**COMPLETION OF FILING REQUIREMENTS  
 FOR INTERNATIONAL APPLICATION ENTERING NATIONAL  
 STAGE IN U.S. DESIGNATED OFFICE (DO/US) UNDER 35 U.S.C. § 371**

*(check and complete the following item, if applicable)*

- ☐ This reply to the Notice of Missing Requirements under 35 U.S.C. § 371 and 37 C.F.R. § 1.494 (FORM PCT/DO/EO/905).  
☐ A copy of FORM PCT/DO/EO/905 accompanies this response.

**CERTIFICATION UNDER 37 C.F.R. §§ 1.8(a) and 1.10\***

*(When using Express Mail, the Express Mail label number is mandatory;  
 Express Mail certification is optional.)*

I hereby certify that, on the date shown below, this correspondence is being:

**MAILING**

- ☐ deposited with the United States Postal Service in an envelope addressed to the Assistant Commissioner for Patents, Washington, D.C. 20231

**37 C.F.R. § 1.8(a)**

**37 C.F.R. § 1.10 \***

- ☐ with sufficient postage as first class mail. ☒ as "Express Mail Post Office to Addressee"  
 Mailing Label No. EK710244307US (mandatory)

**TRANSMISSION**

- ☐ facsimile transmitted to the Patent and Trademark Office, (703) \_\_\_\_\_

Agnes F. Gausman  
 Signature

Date: 10/22/01

Agnes F. Gausman  
 (type or print name of person certifying)

\* Only the date of filing (§ 1.6) will be the date used in a patent term adjustment calculation, although the date on any certificate of mailing or transmission under § 1.8 continues to be taken into account in determining timeliness. See § 1.703(f). Consider "Express Mail Post Office to Addressee" (§ 1.10) or facsimile transmission (§ 1.6(d)) for the reply to be accorded the earliest possible filing date for patent term adjustment calculations.

(Completion of Filing Requirements for International Application Entering National Stage in Designated Office (DO/US) under 35 U.S.C. § 371 [13-8]—page 1 of 6)

1001331-013102

**WARNING:** Where the items being submitted to complete the entry of the international application into the national phase are subsequent to 20 months from the priority date, the application is still considered to be in the international stage. If mailing procedures are utilized to obtain a date, the express mail procedure of 37 C.F.R. § 1.10 must be used (because international application papers are not covered by an ordinary certificate of mailing. 37 C.F.R. § 1.8(2)(xi).

**NOTE:** Documents and fees must be clearly identified as a submission to enter the national stage under 35 U.S.C. § 371. Otherwise, the submission will be considered as being made under 35 U.S.C. § 111. 37 C.F.R. § 1.494(f).

### DECLARATION OR OATH

- I. ☐ No original declaration or oath was filed. Enclosed is the original declaration or oath for this application.

OR

- ☐ The declaration or oath that was filed was determined to be defective. A new original or oath or declaration is attached.

**NOTE:** For surcharge fee for filing declaration after filing date, complete item IV(2).

**NOTE:** Acceptable minimums in the declaration in an ordinarily filed U.S. application for identification of the specification to which it applies are:

(A) application number (consisting of the series code and the serial number, e.g., 08/123,456);

(B) serial number and filing date;

(C) attorney docket number which was on the specification as filed;

(D) title which was on the specification as filed and reference to an attached specification which is both attached to the oath or declaration at the time of execution and submitted with the oath or declaration; or

(E) title which was on the specification as filed and accompanied by a cover letter accurately identifying the application for which it was intended by either the application number (consisting of the series code and the serial number, e.g., 08/123,456), or serial number and filing date. Absent any statement(s) to the contrary, it will be presumed that the application filed in the PTO is the application which the inventor(s) executed by signing the oath or declaration.

M.P.E.P. § 601.01(a), 7th ed. Notice of September 12, 1983 (1035 O.G. 3). See M.P.E.P. § 601.01(a), 7th ed.

**NOTE:** Another minimum found acceptable in the declaration is the filing date (i.e., date of express mail) and the express mail number, useful where the serial number is not yet known. But note the practice where the express mail deposit is a Saturday, Sunday or holiday within the District of Columbia. 37 C.F.R. § 1.10(c).

**NOTE:** 37 C.F.R. § 1.41(a) points out that "Full names must be stated, including the family name and at least one given name without abbreviation together with any other given name or initial."

(complete (a) or (b), if applicable)

Attached is a

- (a) ☐ Statement by a registered attorney that the application filed in the PTO is the application that the inventor executed by signing the declaration.
- (b) ☐ Statement that the "attached" specification is a copy of the specification and any amendments thereto that were filed in the PTO to obtain the filing date.

AMENDMENT

10/018131  
LAW PCT/PTO 22 OCT 2001

II.

(complete as applicable)

- ☐ An amendment in accordance with 37 C.F.R. § 1.121 is attached.  
☐ The attached amendment cancels claims \_\_\_\_\_ inclusively.

**TRANSMITTAL OF ENGLISH TRANSLATION  
OF NON-ENGLISH LANGUAGE PAPERS**

- III. ☒ Submitted herewith, is an English translation of the non-English language international application papers as originally filed. It is requested that this translation be used as the copy for examination purposes in the PTO. (See 37 C.F.R. § 1.494(b)(2)).

NOTE: For fee for processing a non-English application, and submission of an English translation later than 20 months after the priority date, complete item IV(3) below.

NOTE: A non-English oath or declaration in the form provided or approved by the PTO need not be translated. 37 C.F.R. § 1.69(b).

**FEES**

IV.

NOTE: See 37 C.F.R. § 1.28(a).

1. Fees for claims

- ☐ Each independent claim in excess of 3  
(37 C.F.R. § 1.492(b)—\$80.00; small entity—\$40.00) \$ 0  
☐ Each claim in excess of 20  
(37 C.F.R. § 1.492(c)—\$18.00; small entity—\$9.00) \$ 0  
☐ Multiple dependent claim(s)  
(37 C.F.R. § 1.492(d)—\$270.00;  
small entity—\$135.00) \$ 0

2. Surcharge fees

- ☐ Surcharge set forth in § 1.492(e), for accepting the declaration later than 20 months after the priority date in filing an application in the U.S. as a designated office—\$130.00; small entity—\$65.00 \$ 0

NOTE: The processing fee in the next item (Number 3) below is not subject to a reduction for small entity status.

3. ☐ Processing fee set forth in § 1.492(f), for acceptance of an English translation later than 20 months after the priority date—\$130.00 \$ 430.00

Total fees \$ 430.00

(Completion of Filing Requirements for International Application Entering National Stage in Designated Office (DO/US) under 35 U.S.C. § 371 [13-8]—page 3 of 6)

10016131-013102

### SMALL ENTITY STATUS

V. ☐ An assertion that this filing is by a small entity

(check and complete applicable items)

- a. ☐ is attached.  
☐ was filed on \_\_\_\_\_ (original).  
☐ was made by paying the basic national filing fee as a small entity.  
☒ is being made now by paying the basic national filing fee as a small entity.
- b. ☐ A separate refund request accompanies this paper.

### EXTENSION OF TIME

(complete (a) or (b), as applicable)

VI.

The proceedings herein are for a patent application. The provisions of 37 C.F.R. § 1.136(a) apply.

(a) ☐ Applicant petitions for an extension of time, the fees for which are set out in 37 C.F.R. § 1.17(a)(1)-(4), for the total number of months checked out below

<input type="checkbox"/> one month	\$ 110.00	\$ 55.00
<input type="checkbox"/> two months	\$ 390.00	\$ 195.00
<input type="checkbox"/> three months	\$ 890.00	\$ 445.00
<input type="checkbox"/> four months	\$ 1,390.00	\$ 695.00
<input type="checkbox"/> five months	\$ 1,890.00	\$ 945.00

Fee: \$ \_\_\_\_\_

If an additional extension of time is required, please consider this a petition therefore.

(check and complete the next item, if applicable)

- ☐ An extension for \_\_\_\_\_ months has already been secured. The fee paid therefor of \$ \_\_\_\_\_ is deducted from the total fee due for the total months of extension now requested.

Extension fee due with this request \$ \_\_\_\_\_

or

- (b) ☒ Applicant believes that no extension of term is required. However, this conditional petition is being made to provide for the possibility that applicant has inadvertently overlooked the need for a petition and fee for extension of time.

### TOTAL FEE DUE

VII. The total fee due is:

Completion fee(s) \$ 430.00

Extension fee (if any) \$ \_\_\_\_\_

TOTAL FEE DUE \$ 430.00

10018131-013102

**PAYMENT OF FEES****VIII.**

- ☐ Attached is a ☐ check ☐ money order in the amount of \$ \_\_\_\_\_
- ☒ Authorization is hereby made to charge the amount of \$ 1,445.00
- ☐ to Deposit Account No. 13-0760
- ☐ to Credit card as shown on the attached credit card information authorization form PTO-2038.

**WARNING:** Credit card information should *not* be included on this form as it may become public.

- ☒ Charge any additional fees required by this paper or credit any overpayment in the manner authorized above.

A duplicate of this paper is attached.

**AUTHORIZATION TO CHARGE ADDITIONAL FEES****IX.**

**WARNING:** Accurately count claims, especially multiple dependant claims, to avoid unexpected high charges if extra claims are authorized.

**NOTE:** "A written request may be submitted in an application that is an authorization to treat any concurrent or future reply, requiring a petition for an extension of time under this paragraph for its timely submission, as incorporating a petition for extension of time for the appropriate length of time. An authorization to charge all required fees, fees under § 1.17, or all required extension of time fees will be treated as a constructive petition for an extension of time in any concurrent or future reply requiring a petition for an extension of time under this paragraph for its timely submission. Submission of the fee set forth in § 1.17(a) will also be treated as a constructive petition for an extension of time in any concurrent reply requiring a petition for an extension of time under this paragraph for its timely submission." 37 C.F.R. § 1.136(a)(3).

**NOTE:** "Amounts of twenty-five dollars or less will not be returned unless specifically requested within a reasonable time, nor will the payer be notified of such amounts; amounts over twenty-five dollars may be returned by check or, if requested, by credit to a deposit account." 37 C.F.R. § 1.26(a).

- ☐ Please charge, in the manner authorized above, the following additional fees that may be required by this paper and during the entire pendency of this application:
- ☐ 37 C.F.R. §§ 1.492(a)(2), 1.492(a)(3), or 1.492(a)(5) (filing fees)
- ☐ 37 C.F.R. § 1.492(b) (presentation of extra claims)

**NOTE:** Because additional fees for excess or multiple dependent claims not paid on filing, or on later presentation, must only be paid, or these claims cancelled by amendment prior to the expiration of the time period set for response by the PTO in any notice of fee deficiency (37 C.F.R. § 1.16(d)), it might be best not to authorize the PTO to charge additional claim fees, except possibly when dealing with amendments after final action.

- ☐ 37 C.F.R. § 1.17 (application processing fees)
- ☐ 37 C.F.R. § 1.17(a)(1)–(5) (extension fees pursuant to § 1.136(a)).

**WARNING:** While 37 C.F.R. § 1.17(a), (b), (c) and (d) deal with extensions of time under § 1.136(a), this authorization should be made only with the knowledge that: "Submission of the appropriate extension fee under 37 C.F.R. § 1.136(a) is to no avail unless a request or petition for extension is filed." (Emphasis added). Notice of November 5, 1985 (1060 O.G. 27).

- ☐ 37 C.F.R. § 1.18 (issue fee at or before mailing of Notice of Allowance, pursuant to 37 C.F.R. § 1.311(b)).

**NOTE:** Where an authorization to charge the issue fee to a deposit account has been filed before the mailing of a Notice of Allowance, the issue fee will be automatically charged to the deposit account at the time of mailing the notice of allowance. 37 C.F.R. § 1.311(b).

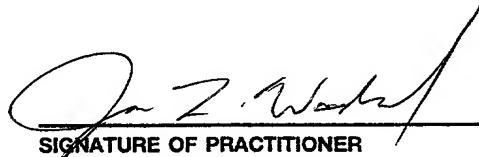
(Completion of Filing Requirements for International Application Entering National Stage in Designated Office (DO/US) under 35 U.S.C. § 371 [13-8]—page 5 of 6)

1001013102

NOTE: 37 C.F.R. § 1.28(b) requires "Notification of any change in loss of entitlement to small entity status must be filed in the application . . . prior to paying, or at the time of paying . . . issue fee." From the wording of 37 C.F.R. § 1.28(b): (a) notification of change of status must be made even if the fee is paid as "other than a small entity" and (b) no notification is required if the change is to another small entity.

- ☐ 37 C.F.R. § 1.492(e) and (f) (surcharge fees for filing the declaration and/or an English translation of an international application later than 20 months from the earliest claimed priority date)

**WARNING:** It is suggested that you always check this last authorization.

  
SIGNATURE OF PRACTITIONER

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U. S. PATENT and TRADEMARK OFFICE

10/018131

In Re Application of: Heinrich Wehberg

Application No: 10/018,131

Filed on: October 22, 2001



Title: Apparatus for Recording a Thermo-optical Image of the Female Breast

*Assistant Commissioner for Patents  
Washington, DC 20231*

### PRELIMINARY AMENDMENT

#### In the Specification

Delete the text on page 1 beginning with line 3, continuing through page 8, and substitute the following:

Like a fingerprint, the vascular pattern in the female breast is individual to every woman and under normal conditions, such patterns remain unchanged. Changes in the vascular pattern of a breast may indicate the presence of a mammary carcinoma or other disorder.

Most conventional methods for detecting and diagnosing mammary carcinomas within the framework of preventive medical examinations, most frequently mammography, incorporate the use of x-rays. These methods lead to a very limited radiation exposure for the patient. As a supplement to mammography, thermography can be used to diagnose mammary carcinomas using skin temperature.

The prior art includes various techniques for performing diagnosis of mammary carcinomas. In one group of methods, skin temperatures are directly measured on the breast. Optionally, such measurements can be further processed electronically. WO 79/00594 and U.S. Patent 3,970,074 disclose apparatuses in which the breast is pressed against a plate equipped with temperature sensors arranged in a matrix-like manner to measure skin temperature. The measured data are electronically processed and specific temperature distributions on the skin are used to indicate the presence of a mammary carcinoma. U.S. Patent 4,055,166 discloses a brassier, which is fitted with individual temperature sensors that monitor skin temperature

January 15, 2002

constantly at corresponding points. Specific changes to the skin temperature indicate the existence of mammary carcinomas.

A second group of thermographic methods include those using plate thermography, such as in the apparatus disclosed by German Patent D.E. 83 26 341 U1. A thermographic plate is pressed onto the female breast, and as a function of temperature, a thermographic coating on the plate assumes different colors. This method renders patterns of vessels optically visible in a thermographic manner, with certain vessel patterns revealing higher levels of heat than other areas. Specific structures or features indicate abnormal changes. The actual diagnostic method of plate thermography is described in greater detail in "Atlas der Plattenthermographie" by G. Lauth and G. Mühlberger. This atlas gives an introduction to physicians inexperienced in plate thermography. However, plate thermography is limited in that successful use requires an experienced and skilled physician. The technique is prone to high rates of error, especially when utilized by an inexperienced physician.

#### SUMMARY

In accordance with the invention, an apparatus facilitates diagnosis of pathological changes in the female breast using the surprising discovery that, by cooling a thermooptical foil for predetermined duration and then illuminating and recording a thermooptical image of the foil, it is possible to standardize thermooptical images to similar and reproducible recording conditions to permit easy and more reliable diagnosis of pathological changes.

The invention records a thermooptical image of the female breast using a thermooptical foil positioned on a frame, the foil being cooled to a standardized and constant temperature. The thermooptical foil is positioned adjacent a casing that is opaque except for the side facing the breast, and a cooling box is positioned between the casing and foil. The foil is also positioned to contact the breast, and a timer measures a presettable amount of time that passes after the cooling box begins to cool the foil. The cooling box causes a constant temperature to be established throughout the thermooptical foil, allowing for standardized and reproducible recording conditions. An illuminating system illuminates the thermooptical foil from within the casing and a digital camera is used to record image data from the illuminated foil for evaluation and diagnosis. A triggering



mechanism is used to operate the digital camera so that the camera makes its photographic recording of the breast at the end of the presettable amount of time that passes after the cooling box begins to cool the foil.

To effect cooling of the thermo-optical foil, the cooling box can use a cooling medium fluid such as water supplied by a cooling medium circuit. The cooling medium circuit includes a cooling medium inlet and a cooling medium outlet, with an adjustable thermostat being used to measure the amount of cooling performed and being responsive to the temperature of the cooling medium. The cooling box can be transparent and an antireflection disk can also be positioned between the cooling box and digital camera.

The foil can have an initial position in which it is not in contact with the cooling box. Pins, springs, or other devices can be included to permit surface contact between the foil and cooling box, and a locking device can be included to fix the foil in place after making contact with the cooling box. A clamping device can also be included in the apparatus for clamping the breast against the foil. In some embodiments, a pad can be used in the clamping device to press the breast against the foil and can be variably spaced from the foil.

In some embodiments, the casing, cooling box, and foil can all be mounted on a multi-articulation arm to permit positioning of apparatus components with respect to the patient being examined. The multi-articulation arm can be mounted on an instrument trolley to permit easy handling of the casing and easy transportation of the apparatus.

Some embodiments of the invention include a monitor screen connected to the digital camera to permit the observation of images as they are viewed through the camera. A computer and keyboard can also be included to operate the triggering mechanism and manipulate image data recorded by the digital camera. Various other types of output devices, such as printers and various facilities for storing digital images recorded by the camera, such as diskette and CD-ROM devices, can also be included.

In some embodiments, image evaluating devices connected to the digital camera can permit automatic evaluation of information contained in the recorded image for the existence of a pathological change or for features characteristic of mammary carcinomas. An image evaluating device can also be configured to compare recorded images with earlier images of the same breast or with reference images. In some embodiments, the

monitor screen can be subdivided into two windows, one window being used for displaying the present image and the other window being used for displaying an earlier image of the same breast or a reference image.

Those skilled in the art will realize that this invention is capable of embodiments which are different from those shown in that the details of the structure of the recording apparatus disclosed herein can be changed in various manners without departing from the scope of this invention. Accordingly, the drawings and description are to be regarded as illustrative in nature and are not to restrict the scope of the invention. Additionally, the claims are to be regarded as including such equivalent recording apparatuses as do not depart from the nature and scope of this invention.

### BRIEF DESCRIPTION OF THE DRAWINGS

For a more complete understanding and appreciation of this invention and many of its advantages, reference will be made to the following Detailed Description of the Preferred Embodiments taken in conjunction with the accompanying drawings:

FIG. 1 is a diagrammatic side view of part of one embodiment of an apparatus for recording a thermo-optical image of the female breast according to the invention;

FIG. 2 is another part of the apparatus of FIG. 1; and

FIG. 3 diagrammatically represents the combined apparatus including the components depicted in FIGS. 1 and 2 as used on a patient.

### DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

Referring now to the drawings, identical reference numerals and letters designate the same or corresponding parts throughout the several figures shown in the drawings.

FIG. 1 diagrammatically depicts a side view of part of a special embodiment of the apparatus according to the invention. The apparatus comprises a casing 4 which, for standardizing the thermo-optical images, is opaque except on the side facing the breast where a frame 9 is mounted. This configuration permits image recording to be free from external reflections. A film or thermo-optical foil 1 is positioned on the frame 9. A cooler or transparent cooling box 7 and an antireflection disk 6 are placed between the foil 1 and casing

4, with the antireflection disk 6 being placed closer toward the interior of the casing 4 and forming the interior wall of the cooling box 7. The foil 1 can be stretched over the narrow frame 9 and be biased to a relaxed state position (as shown in FIG. 1) that is two to three centimeters in front of a front wall 8 of the cooling box 7. The quadrangular frame 9 is held in the four corners of the casing 4 by steel pins 10 and the spacing of the foil 1 from the front wall of the cooling box 7 is maintained by four springs 11. The springs 11 are inverted over the pins 10 and in the relaxed state are sufficiently long to hold the foil 1 at the relaxed state position away from the front wall 8 of the cooling box 7. The springs 11 and frame 9 are configured so that sufficient spacing exists between the foil 1 and casing 4 to permit adjustments and corrections to the position of the foil 1 after the breast is placed against the foil 1 without creating surface contact between the foil 1 and the front wall 8 of the cooling box 7.

The cooling box 7 has a cooling medium inlet 12a and a cooling medium outlet 12b connecting the cooling box 7 in a circuit with a thermostat 17 by means of hose lines 12c (cf. FIG. 2). The cooling medium can be a fluid such as water. Continuous water circulation through the cooling medium inlet 12a and cooling medium outlet 12b and constant water temperature ensure the constancy of the temperature of the foil 1. Based on the thermal sensitivity of the foil 1, the set cooling should always be constant. Some embodiments of the invention can allow the operator of the apparatus to perform manual, computer-controlled adjustment of the degree of cooling by the cooling medium, the operator issuing control commands to a computer 3 (cf. FIG. 2) through keyboard 13 (cf. FIG. 2).

A digital camera 2 is positioned inside the casing 4, the digital camera 2 being positioned to record images in the direction of the frame 9. An illuminating system comprises two lamps 5 for illuminating the foil 1, the lamps 5 of the illuminating system being oriented to optimize the recordings of the digital camera 2. In addition, the illumination provided by the lamps 5 contributes to the creation of standardized recording conditions.

A clamping mechanism that includes a pad 14 and mounting support 15 is mounted on the apparatus to gently clamp the breast against the foil 1. As shown in FIG. 1, the mounting support 15 defines a horizontal plane in which the spacing between the pad 14 and foil 1 can be varied by moving the pad 14 along the horizontal plane toward and away from the foil 1. Varying the spacing between the pad 14 and foil 1 enables the breast to be pressed gently but firmly against the foil 1 which further assists in the creation of standardized recording conditions.

FIG. 2 diagrammatically depicts another part of the apparatus of FIG. 1. A thermostat 17, a computer 3 with a keyboard 13 and a screen 16 are located in an instrument trolley 19. Referring briefly to FIG. 3, a multi-articulation arm 18 is mounted on the trolley 19, the multi-articulation arm 18 supporting the casing 4 and being extendable to orient the casing 4 into various mobile positions. Some embodiments permit the multi-articulation arm 18 to be locked in order to orient the casing in a fixed position relative to the patient. The multi-articulation arm 18 can also be hollow in order to accommodate power, communication, hosing, and other supply lines to the digital camera 2, cooling box 7, and components of the illuminating system 5.

Referring now to FIG. 3, the connected casing 4 and trolley 19 are represented, the cooling box 7, foil 1, and pad 14 being depicted in an exploded view with the foil 1 being rotated approximately 90° for the purpose of further functional description. The placement of the thermo-optical foil 1 on the female breast results in a heat pattern, represented by different colors corresponding to the areal thermal states of the skin, to appear on the foil 1. This thermal pattern is reversible after the foil 1 has been removed from the breast. Cooling the foil 1 has the effect of minimizing coloration of the foil 1, with color patterns becoming more sharply contoured and with contrast to the black background being improved. Cooling the foil has the added effect of reducing the effect that surface or "skin heat" has on the foil coloration, the foil coloration instead displaying and representing peaks of heat dissipated from more low-lying heat sources deep beneath the surface of the breast.

In the operation of the recording apparatus, recording positions correspond to those for mammography, but with the difference that in the case of breasts of normal size, two lateral and two craniocaudal exposures are made for each breast. The reason for this difference is that in "vascugraphy" emitted heat is measured and greater accuracy can be obtained in results by measuring from both sides. After the breast and foil 1 come into contact, the breast is held with the soft pad 14 which the patient can position herself. This is advantageous in that it tends to avoid discomfort associated with the squeezing examination that patients often experience during mammography.

The duration of time in which the foil is cooled is also significant and must be defined and measured in order to establish standardized recording conditions during the cooling process. For example, cooling time can be measured from the instant when the foil 1 is gently pressed counter to the tension of springs 10 on a cooling box 7 and when a locking means (not shown) snaps into a locked position accordingly. At that time, a timing system (not shown) begins to measure the amount of time that passes as the cooling process continues. At the end of a presettable amount of time, the timing system operates a triggering mechanism (not shown) which is used to operate the digital camera 2 to shoot or record the image on the thermooptical foil 1. After completion of the image recording, the pad 14 can be returned to its initial, pre-clamping position to release pressure against the breast. In some embodiments, the releasing action can be provided mechanically with a gas spring pressure mechanism (not shown) incorporated into the mounting support 15. Recording conditions can therefore be standardized by reproducing conditions or "settings" such as the cooling temperature and duration of the cooling period.

During recording or shooting of the thermooptical image by the digital camera 2, all settings can be monitored on the monitor screen 16. The monitor screen further displays all image data being recorded by the digital camera 2. The dimensions of the foil 1 correspond to those of a mammographic film with a size, for example, of 18 x 24 centimeters. On replacing the foil 1 by a finished mammographic image (e.g. a positive case) and homogeneous transillumination of the film from the outside in the direction of the digital camera 2, it is possible to obtain a simple, inexpensive form of digitized storage of the mammogram for the particular

patient. The congruent superimposing of the thermal image and the mammogram on the screen can provide valuable information to the diagnosing doctor. The thermooptical image recorded by the digital camera 2 can then be transferred to the computer 3, where an image evaluation facility can perform an automatic evaluation of the image by utilizing appropriate software. Other types of output devices for storing digital images recorded by the digital camera 16 are also contemplated to be within the scope of the invention and include but are not limited to printed output devices, diskettes, and CD-ROM devices.

The invention can allow for automatic or electronic interpretation of thermooptical images without necessarily requiring the interpretation skills of an examining physician. Pathological changes can be detected by comparing the thermographically obtained vascular pattern and shape of the patient's vessels with reference data, as is particularly appropriate during the initial examinations of a particular patient. However, if previous recordings or exposures exist, it is also possible to carry out a comparison of the current recorded image with one or more images recorded previously. The invention may include a facility for displaying a current recorded image next to a previous recorded image in a split-window fashion. Changes in the thermooptical image may indicate changes in the vascular pattern of the breast which in turn may indicate a pathological change warranting further investigation with another more intrusive diagnostic technique such as a biopsy.

Many other modifications and changes can be made to the recording device of this invention by those skilled in the art without departing from the spirit and scope of this invention. Thus, the claims when appended are intended to be interpreted to cover such equivalent recording apparatuses as do not depart from the spirit and scope of this invention.

#### In the Claims

**Please cancel claims 1-16 and add the following claims:**

1. An apparatus for recording a thermooptical image of a female breast on a thermooptical foil comprising:

a casing having a non-opaque side, said non-opaque side being positioned to face a location for the breast when the thermooptical image is recorded;

a thermooptical foil for producing a thermooptical image of the breast having at least first and second surfaces and being positioned between said casing and the location for the breast, said first surface of said thermooptical foil facing said non-opaque side of said casing, said second surface of said thermooptical foil being positioned to contact the breast;

a transparent cooling apparatus which can contact and cool said thermooptical foil to a constant temperature for a presettable amount of time when said thermooptical foil is in contact with the breast; and

a camera mounted to record from within said casing the thermooptical image of the foil against the breast at the end of the presettable amount of time.

18. The apparatus for recording a thermooptical image of a female breast of claim 17 further comprising an illuminating system for illuminating said thermooptical foil within said casing.

19. The apparatus for recording a thermooptical image of a female breast of claim 17, said cooling apparatus being configured to cool said thermooptical foil to a constant temperature to allow for standardized and reproducible recording conditions.

20. An apparatus for recording a thermooptical image of a female breast comprising:

a casing having at least one opaque side and a non-opaque side, said non-opaque side being positioned to face a location for the breast when the image is recorded;

a thermooptical foil for producing a thermooptical image of the breast having at least first and second surfaces and being positioned on a frame located between said casing and the location for the breast, said first surface of said thermooptical foil facing said non-opaque side of said casing, said second surface of said thermooptical foil being positioned to contact the breast;

a cooling box mounted adjacent said first surface of said thermooptical foil for cooling said thermooptical foil to a standard temperature at a time when said thermooptical foil contacts the breast;

a timer for measuring a presettable amount of time that passes after said thermooptical foil begins to be cooled by said cooling box;

an illuminating system for illuminating said thermooptical foil within said casing; and

a digital camera positioned to record the thermooptical image of the breast on said thermooptical foil from within said casing after the presettable amount of time passes.

21. The apparatus for recording a thermooptical image of claim 20 further comprising a cooling medium circuit for providing a cooling medium to effect cooling of said cooling box, said cooling medium circuit comprising:

a cooling medium inlet for supplying said cooling medium to said cooling box;

a cooling medium outlet for removing said cooling medium from said cooling box; and

a thermostat for measuring the amount of cooling performed by said cooling medium circuit, said thermostat being responsive with respect to the temperature of said cooling medium.

22. The apparatus for recording a thermooptical image of claim 20 further comprising an antireflection disk positioned between said thermooptical foil and said digital camera.

23. The apparatus for recording a thermooptical image of claim 20, said thermooptical foil having a relaxed position, said thermooptical foil does not come into contact with said cooling box when in the relaxed position.

24. The apparatus for recording a thermooptical image of claim 20, said frame having a relaxed position and being springingly connected to said casing with at least one mounting device, each said at least one mounting device comprising:

a steel pin extending from said frame to said casing; and

a spring having an unloaded condition and an unloaded length and being inverted over said steel pin, said spring extending from said frame to said casing, wherein said spring assumes said unloaded length when assuming said unloaded condition, said unloaded length of said spring being sufficient to maintain a spacial clearance between said cooling box and said thermooptical foil.



25. The apparatus for recording a thermooptical image of claim 24, compression of each said spring permits said frame to assume a non-relaxed position and further permits contact between said thermooptical foil and said cooling box.

26. The apparatus for recording a thermooptical image of claim 20 further comprising a clamping device having a pad for pressing the breast against said thermooptical foil.

27. The apparatus for recording a thermooptical image of claim 20 further comprising a clamping device for clamping the breast against said thermooptical foil, said clamping device comprising:

a pad for pressing the breast against said thermooptical foil; and

a mounting support for providing support for said pad and for providing pressure for said pad against said breast.

28. The apparatus for recording a thermooptical image of claim 20 further comprising a clamping device comprising:

a pad for pressing the breast against said thermooptical foil; and

a mounting support connected to said casing, said mounting support extending parallel to said frame for providing support for said pad, the spacing between said pad and said thermooptical foil being variable.

29. The apparatus for recording a thermooptical image of claim 20 having a clamping device comprising:

a pad for pressing the breast against said thermooptical foil, said pad having a major planar pressing surface; and

a mounting support having a major horizontal dimension and being connected to said casing, said mounting support providing support for said pad, the spacing between said pad and said thermooptical foil being variable, said major planar pressing surface of said pad positioned at about a right angle to said major horizontal dimension of said mounting support.

30. The apparatus for recording a thermooptical image of claim 20 further comprising:

said frame having a relaxed position, a substantially quadrangular shape, first, second, third and fourth corners, and being springingly connected to said casing with one steel pin in each said corner of said frame, each said steel pin extending from said frame to said casing;

each said steel pin having a spring, each said spring having an unloaded condition and an unloaded length and being inverted over said pin, each said spring extending from said frame to said casing wherein said spring assumes said unloaded length when assuming said unloaded condition, said unloaded length of said spring being sufficient to maintain a spacial clearance between said cooling box and said thermooptical foil.

31. The apparatus for recording a thermooptical image of claim 30, compression of said springs permits said frame to assume a non-relaxed position and further permits contact between said thermooptical foil and said cooling box.

32. The apparatus for recording a thermooptical image of claim 20, said casing being positioned on a multi-articulation arm to permit variable positioning of said casing.

33. The apparatus for recording a thermooptical image of claim 20, said casing being positioned on a multi-articulation arm mounted on an instrument trolley to permit variable positioning of said casing with respect to said instrument trolley.

34. The apparatus for recording a thermooptical image of claim 20 further comprising a monitor screen connected to said digital camera for monitoring images recorded with said digital camera.

35. The apparatus for recording a thermooptical image of claim 20 further comprising a computer for processing images collected with said digital camera.

36. The apparatus for recording a thermooptical image of claim 20 further comprising a computer for operating said apparatus and for processing information collected with said digital camera.

37. The apparatus for recording a thermooptical image of claim 20 further comprising an information storage medium for storing digital images recorded with said digital camera.

38. The apparatus for recording a thermooptical image of claim 20 further comprising printer output device for producing digital images recorded with said digital camera in a printed format.

39. The apparatus for recording a thermooptical image of claim 20 further comprising an image evaluating device connected to said digital camera for automatic evaluation of information contained in images recorded with said digital camera in response to pathological changes.

40. The apparatus for recording a thermooptical image of claim 20 further comprising an image evaluating device connected to said digital camera for comparing information contained in images recorded with said digital camera to reference images.

41. The apparatus for recording a thermooptical image of claim 20 further comprising an image evaluating device connected to said digital camera for comparing an image recorded by said digital camera for structures or features characteristic of mammary carcinomas.

42. The apparatus for recording a thermooptical image of claim 20 further comprising a monitor screen, said monitor screen being subdivided into first and second windows, said first window configured to display the image recorded by said digital camera, said second image configured to display a reference image for comparison to said first window.

43. An apparatus for recording a thermooptical image of a female breast comprising:

a casing having at least one opaque side and a non-opaque side, said non-opaque side being positioned to face a location for the breast when the image is recorded;

a thermooptical foil for producing a thermooptical image of the breast having at least first and second surfaces and being positioned on a frame located between said casing and the location for the breast, said first surface of said thermooptical foil facing said non-opaque side of said casing, said second surface of said thermooptical foil being positioned to contact the breast;

said frame having a relaxed position, a substantially quadrangular shape, first, second, third and fourth corners, and being springingly connected to said casing with one steel pin in each said corner of said frame, each said steel pin extending from said frame to said casing and having a spring, each said spring having an unloaded condition and an unloaded length and being inverted over said pin, each said spring extending from said frame to said casing wherein said spring assumes said unloaded length when assuming said unloaded

condition, said unloaded length of said spring being sufficient to maintain a spacial clearance between said cooling box and said thermooptical foil, compression of said springs permits said frame to assume a non-relaxed position and further permits contact between said thermooptical foil and said cooling box;

a clamping device for clamping the breast against said thermooptical foil, said clamping device having a pad for pressing the breast against said thermooptical foil and a mounting support for providing support for said pad and for providing pressure for said pad against said breast;

a cooling box mounted adjacent said first surface of said thermooptical foil for cooling said thermooptical foil to a standard temperature at a time when said thermooptical foil contacts the breast;

a cooling medium circuit for providing a cooling medium to effect cooling of said cooling box, said cooling medium circuit having a cooling medium inlet for supplying said cooling medium to said cooling box, a cooling medium outlet for removing said cooling medium from said cooling box, and a thermostat for measuring the amount of cooling performed by said cooling medium circuit, said thermostat being responsive to the temperature of said cooling medium;

a timer for measuring a presettable amount of time that passes after said thermooptical foil begins to be cooled by said cooling box;

an illuminating system for illuminating said thermooptical foil within said casing; and

a digital camera positioned to record the thermooptical image of the breast on said thermooptical foil from within said casing after the presettable amount of time passes; and

an antireflection disk positioned between said thermooptical foil and said digital camera.

44. An apparatus for recording a thermooptical image of a female breast comprising:

a casing having at least one opaque side and a non-opaque side, said non-opaque side being positioned to face a location for the breast when the image is recorded, said casing being positioned on a multi-articulation arm mounted on an instrument trolley to permit variable positioning of said casing with respect to said instrument trolley;

a thermooptical foil for producing a thermooptical image of the breast having at least first and second surfaces and being positioned on a frame located between said casing and the location for the breast, said first surface of said thermooptical foil facing said non-opaque side of said casing, said second surface of said thermooptical foil being positioned to contact the breast;

said frame having a relaxed position, a substantially quadrangular shape, first, second, third and fourth corners, and being springingly connected to said casing with one steel pin in each said corner of said frame, each said steel pin extending from said frame to said casing and having a spring, each said spring having an unloaded condition and an unloaded length and being inverted over said pin, each said spring extending from said frame to said casing wherein said spring assumes said unloaded length when assuming said unloaded condition, said unloaded length of said spring being sufficient to maintain a spacial clearance between said cooling box and said thermooptical foil, compression of said springs permits said frame to assume a non-relaxed position and further permits contact between said thermooptical foil and said cooling box;

a clamping device for clamping the breast against said thermooptical foil, said clamping device having a pad for pressing the breast against said thermooptical foil and a mounting support for providing support for said pad and for providing pressure for said pad against said breast;

a cooling box mounted adjacent said first surface of said thermooptical foil for cooling said thermooptical foil to a standard temperature at a time when said thermooptical foil contacts the breast;

a cooling medium circuit for providing a cooling medium to effect cooling of said cooling box, said cooling medium circuit having a cooling medium inlet for supplying said cooling medium to said cooling box, a cooling medium outlet for removing said cooling medium from said cooling box, and a thermostat for measuring the amount of cooling performed by said cooling medium circuit, said thermostat being responsive to the temperature of said cooling medium;

a timer for measuring a presettable amount of time that passes after said thermooptical foil begins to be cooled by said cooling box;

an illuminating system for illuminating said thermooptical foil within said casing; and

a digital camera positioned to record the thermooptical image of the breast on said thermooptical foil from within said casing after the presettable amount of time passes;

an antireflection disk positioned between said thermooptical foil and said digital camera;

a monitor screen connected to said digital camera for monitoring images recorded with said digital camera; and

a computer for operating said apparatus and for processing information collected with said digital camera.

45. A method of recording a thermooptical image of a female breast on a thermooptical foil comprising: positioning the thermooptical foil against a breast;

cooling the thermooptical foil to a constant temperature for a presettable amount of time while the thermooptical foil is against the breast; and

recording a thermooptical image of the foil against the breast at the end of the presettable amount of time.

46. The method of claim 45 which includes recording the thermooptical image from within a casing which is opaque except for a side facing the thermooptical foil and illuminating the thermooptical foil at the time of recording the thermooptical image.

47. The method of claim 45 in which the thermooptical image recorded is examined for pathological changes in the breast.

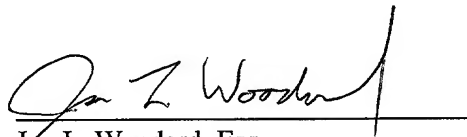
48. The method of claim 45 in which the thermooptical image recorded is compared to a previously recorded thermooptical image for comparison and evaluation of pathological changes.

REMARKS

These amendments in the specification and claims are made to correct inherent translation-related problems with the language of the priority document. A version of the translation was filed as the original U.S. national phase application. No new technical matter has been added or is otherwise unsupported by the amendments contained herein.

Respectfully submitted,

Date: January 16, 2002

  
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I hereby certify that this correspondence is, on the date shown below, being deposited with the United States Postal Service with sufficient postage as first class mail, in an envelope addressed to the Assistant Commissioner for Patents, Washington, D.C. 20231.

Date: January 16, 2002

  
Patty Eckman

***THE FOLLOWING PAGES SHOW CHANGES MADE TO SPECIFICATION:***

Like a fingerprint, the vascular pattern in the female breast is individual to every woman and under normal conditions, such patterns remain unchanged. Changes in the vascular pattern of a breast may indicate the presence of a mammary carcinoma or other disorder.

Most conventional methods for detecting and diagnosing mammary carcinomas within the framework of preventive medical examinations, most frequently mammography, incorporate the use of x-rays. These methods lead to a very limited radiation exposure for the patient. As a supplement to mammography, thermography can be used to diagnose mammary carcinomas using skin temperature.

The prior art includes various techniques for performing diagnosis of mammary carcinomas. In one group of methods, skin temperatures are directly measured on the breast. Optionally, such measurements can be further processed electronically. WO 79/00594 and U.S. Patent 3,970,074 disclose apparatuses in which the breast is pressed against a plate equipped with temperature sensors arranged in a matrix-like manner to measure skin temperature. The measured data are electronically processed and specific temperature distributions on the skin are used to indicate the presence of a mammary carcinoma. U.S. Patent 4,055,166 discloses a brassier, which is fitted with individual temperature sensors that monitor skin temperature constantly at corresponding points. Specific changes to the skin temperature indicate the existence of mammary carcinomas.

A second group of thermographic methods include those using plate thermography, such as in the apparatus disclosed by German Patent D.E. 83 26 341 U1. A thermographic plate is pressed onto the female breast, and as a function of temperature, a thermographic coating on the plate assumes different colors. This method renders patterns of vessels optically visible in a thermographic manner, with certain vessel patterns revealing higher levels of heat than other areas. Specific structures or features indicate abnormal changes. The actual diagnostic method of plate thermography is described in greater detail in "Atlas der



Plattenthermographie” by G. Lauth and G. Mühlberger. This atlas gives an introduction to physicians inexperienced in plate thermography. However, plate thermography is limited in that successful use requires an experienced and skilled physician. The technique is prone to high rates of error, especially when utilized by an inexperienced physician.

### SUMMARY

In accordance with the invention, an apparatus facilitates diagnosis of pathological changes in the female breast using the surprising discovery that, by cooling a thermooptical foil for predetermined duration and then illuminating and recording a thermooptical image of the foil, it is possible to standardize thermooptical images to similar and reproducible recording conditions to permit easy and more reliable diagnosis of pathological changes.

The invention records a thermooptical image of the female breast using a thermooptical foil positioned on a frame, the foil being cooled to a standardized and constant temperature. The thermooptical foil is positioned adjacent a casing that is opaque except for the side facing the breast, and a cooling box is positioned between the casing and foil. The foil is also positioned to contact the breast, and a timer measures a presettable amount of time that passes after the cooling box begins to cool the foil. The cooling box causes a constant temperature to be established throughout the thermooptical foil, allowing for standardized and reproducible recording conditions. An illuminating system illuminates the thermooptical foil from within the casing and a digital camera is used to record image data from the illuminated foil for evaluation and diagnosis. A triggering mechanism is used to operate the digital camera so that the camera makes its photographic recording of the breast at the end of the presettable amount of time that passes after the cooling box begins to cool the foil.

To effect cooling of the thermooptical foil, the cooling box can use a cooling medium fluid such as water supplied by a cooling medium circuit. The cooling medium circuit includes a cooling medium inlet and a cooling medium outlet, with an adjustable thermostat being used to measure the amount of cooling performed and being responsive to the temperature of the cooling medium. The cooling box can be transparent and an antireflection disk can also be positioned between the cooling box and digital camera.

The foil can have an initial position in which it is not in contact with the cooling box. Pins, springs, or other devices can be included to permit surface contact between the foil and cooling box, and a locking device can be included to fix the foil in place after making contact with the cooling box. A clamping device can also be included in the apparatus for clamping the breast against the foil. In some embodiments, a pad can be used in the clamping device to press the breast against the foil and can be variably spaced from the foil.

In some embodiments, the casing, cooling box, and foil can all be mounted on a multi-articulation arm to permit positioning of apparatus components with respect to the patient being examined. The multi-articulation arm can be mounted on an instrument trolley to permit easy handling of the casing and easy transportation of the apparatus.

Some embodiments of the invention include a monitor screen connected to the digital camera to permit the observation of images as they are viewed through the camera. A computer and keyboard can also be included to operate the triggering mechanism and manipulate image data recorded by the digital camera. Various other types of output devices, such as printers and various facilities for storing digital images recorded by the camera, such as diskette and CD-ROM devices, can also be included.

In some embodiments, image evaluating devices connected to the digital camera can permit automatic evaluation of information contained in the recorded image for the existence of a pathological change or for features characteristic of mammary carcinomas. An image evaluating device can also be configured to compare recorded images with earlier images of the same breast or with reference images. In some embodiments, the monitor screen can be subdivided into two windows, one window being used for displaying the present image and the other window being used for displaying an earlier image of the same breast or a reference image.

Those skilled in the art will realize that this invention is capable of embodiments which are different from those shown in that the details of the structure of the recording apparatus disclosed herein can be changed in various manners without departing from the scope of this invention. Accordingly, the drawings and description are to be regarded as illustrative in nature and are not to restrict the scope of the invention.

Additionally, the claims are to be regarded as including such equivalent recording apparatuses as do not depart from the nature and scope of this invention.

### BRIEF DESCRIPTION OF THE DRAWINGS

For a more complete understanding and appreciation of this invention and many of its advantages, reference will be made to the following Detailed Description of the Preferred Embodiments taken in conjunction with the accompanying drawings:

FIG. 1 is a diagrammatic side view of part of one embodiment of an apparatus for recording a thermo-optical image of the female breast according to the invention;

FIG. 2 is another part of the apparatus of FIG. 1; and

FIG. 3 diagrammatically represents the combined apparatus including the components depicted in FIGS. 1 and 2 as used on a patient.

### DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

Referring now to the drawings, identical reference numerals and letters designate the same or corresponding parts throughout the several figures shown in the drawings.

FIG. 1 diagrammatically depicts a side view of part of a special embodiment of the apparatus according to the invention. The apparatus comprises a casing 4 which, for standardizing the thermo-optical images, is opaque except on the side facing the breast where a frame 9 is mounted. This configuration permits image recording to be free from external reflections. A film or thermo-optical foil 1 is positioned on the frame 9. A cooler or transparent cooling box 7 and an antireflection disk 6 are placed between the foil 1 and casing 4, with the antireflection disk 6 being placed closer toward the interior of the casing 4 and forming the interior wall of the cooling box 7. The foil 1 can be stretched over the narrow frame 9 and be biased to a relaxed state position (as shown in FIG. 1) that is two to three centimeters in front of a front wall 8 of the cooling box 7. The quadrangular frame 9 is held in the four corners of the casing 4 by steel pins 10 and the spacing of the foil 1 from the front wall of the cooling box 7 is maintained by four springs 11. The springs 11 are inverted over the pins 10 and in the relaxed state are sufficiently long to hold the foil 1 at the relaxed state position away from

the front wall 8 of the cooling box 7. The springs 11 and frame 9 are configured so that sufficient spacing exists between the foil 1 and casing 4 to permit adjustments and corrections to the position of the foil 1 after the breast is placed against the foil 1 without creating surface contact between the foil 1 and the front wall 8 of the cooling box 7.

The cooling box 7 has a cooling medium inlet 12a and a cooling medium outlet 12b connecting the cooling box 7 in a circuit with a thermostat 17 by means of hose lines 12c (cf. FIG. 2). The cooling medium can be a fluid such as water. Continuous water circulation through the cooling medium inlet 12a and cooling medium outlet 12b and constant water temperature ensure the constancy of the temperature of the foil 1. Based on the thermal sensitivity of the foil 1, the set cooling should always be constant. Some embodiments of the invention can allow the operator of the apparatus to perform manual, computer-controlled adjustment of the degree of cooling by the cooling medium, the operator issuing control commands to a computer 3 (cf. FIG. 2) through keyboard 13 (cf. FIG. 2).

A digital camera 2 is positioned inside the casing 4, the digital camera 2 being positioned to record images in the direction of the frame 9. An illuminating system comprises two lamps 5 for illuminating the foil 1, the lamps 5 of the illuminating system being oriented to optimize the recordings of the digital camera 2. In addition, the illumination provided by the lamps 5 contributes to the creation of standardized recording conditions.

A clamping mechanism that includes a pad 14 and mounting support 15 is mounted on the apparatus to gently clamp the breast against the foil 1. As shown in FIG. 1, the mounting support 15 defines a horizontal plane in which the spacing between the pad 14 and foil 1 can be varied by moving the pad 14 along the horizontal plane toward and away from the foil 1. Varying the spacing between the pad 14 and foil 1 enables the breast to be pressed gently but firmly against the foil 1 which further assists in the creation of standardized recording conditions.

FIG. 2 diagrammatically depicts another part of the apparatus of FIG. 1. A thermostat 17, a computer 3 with a keyboard 13 and a screen 16 are located in an instrument trolley 19. Referring briefly to FIG. 3, a multi-articulation arm 18 is mounted on the trolley 19, the multi-articulation arm 18 supporting the casing 4 and being extendable to orient the casing 4 into various mobile positions. Some embodiments permit the multi-articulation arm 18 to be locked in order to orient the casing in a fixed position relative to the patient. The multi-articulation arm 18 can also be hollow in order to accommodate power, communication, hosing, and other supply lines to the digital camera 2, cooling box 7, and components of the illuminating system 5.

Referring now to FIG. 3, the connected casing 4 and trolley 19 are represented, the cooling box 7, foil 1, and pad 14 being depicted in an exploded view with the foil 1 being rotated approximately 90° for the purpose of further functional description. The placement of the thermooptical foil 1 on the female breast results in a heat pattern, represented by different colors corresponding to the areal thermal states of the skin, to appear on the foil 1. This thermal pattern is reversible after the foil 1 has been removed from the breast. Cooling the foil 1 has the effect of minimizing coloration of the foil 1, with color patterns becoming more sharply contoured and with contrast to the black background being improved. Cooling the foil has the added effect of reducing the effect that surface or "skin heat" has on the foil coloration, the foil coloration instead displaying and representing peaks of heat dissipated from more low-lying heat sources deep beneath the surface of the breast.

In the operation of the recording apparatus, recording positions correspond to those for mammography, but with the difference that in the case of breasts of normal size, two lateral and two craniocaudal exposures are made for each breast. The reason for this difference is that in "vascugraphy" emitted heat is measured and greater accuracy can be obtained in results by measuring from both sides. After the breast and foil 1 come into contact, the breast is held with the soft pad 14 which the patient can position herself. This is advantageous in that it tends to avoid discomfort associated with the squeezing examination that patients often experience during mammography.



The invention can allow for automatic or electronic interpretation of thermooptical images without necessarily requiring the interpretation skills of an examining physician. Pathological changes can be detected by comparing the thermographically obtained vascular pattern and shape of the patient's vessels with reference data, as is particularly appropriate during the initial examinations of a particular patient. However, if previous recordings or exposures exist, it is also possible to carry out a comparison of the current recorded image with one or more images recorded previously. The invention may include a facility for displaying a current recorded image next to a previous recorded image in a split-window fashion. Changes in the thermooptical image may indicate changes in the vascular pattern of the breast which in turn may indicate a pathological change warranting further investigation with another more intrusive diagnostic technique such as a biopsy.

Many other modifications and changes can be made to the recording device of this invention by those skilled in the art without departing from the spirit and scope of this invention. Thus, the claims when appended are intended to be interpreted to cover such equivalent recording apparatuses as do not depart from the spirit and scope of this invention.

### Claims

1. An apparatus for recording a thermooptical image of a female breast on a thermooptical foil comprising:

a casing having a non-opaque side, said non-opaque side being positioned to face a location for the breast when the thermooptical image is recorded;

a thermooptical foil for producing a thermooptical image of the breast having at least first and second surfaces and being positioned between said casing and the location for the breast, said first surface of said thermooptical foil facing said non-opaque side of said casing, said second surface of said thermooptical foil being positioned to contact the breast;

a transparent cooling apparatus which can contact and cool said thermooptical foil to a constant temperature for a presettable amount of time when said thermooptical foil is in contact with the breast; and

a camera mounted to record from within said casing the thermooptical image of the foil against the breast at the end of the presettable amount of time.

2. The apparatus for recording a thermooptical image of a female breast of claim 1 further comprising an illuminating system for illuminating said thermooptical foil within said casing.

3. The apparatus for recording a thermooptical image of a female breast of claim 1, said cooling apparatus being configured to cool said thermooptical foil to a constant temperature to allow for standardized and reproducible recording conditions.

4. An apparatus for recording a thermooptical image of a female breast comprising:  
a casing having at least one opaque side and a non-opaque side, said non-opaque side being positioned to face a location for the breast when the image is recorded;

a thermooptical foil for producing a thermooptical image of the breast having at least first and second surfaces and being positioned on a frame located between said casing and the location for the breast, said first surface of said thermooptical foil facing said non-opaque side of said casing, said second surface of said thermooptical foil being positioned to contact the breast;

a cooling box mounted adjacent said first surface of said thermooptical foil for cooling said thermooptical foil to a standard temperature at a time when said thermooptical foil contacts the breast;

a timer for measuring a presettable amount of time that passes after said thermooptical foil begins to be cooled by said cooling box;

an illuminating system for illuminating said thermooptical foil within said casing; and  
a digital camera positioned to record the thermooptical image of the breast on said thermooptical foil from within said casing after the presettable amount of time passes.

5. The apparatus for recording a thermooptical image of claim 4 further comprising a cooling medium circuit for providing a cooling medium to effect cooling of said cooling box, said cooling medium circuit comprising:

a cooling medium inlet for supplying said cooling medium to said cooling box;



a cooling medium outlet for removing said cooling medium from said cooling box; and

a thermostat for measuring the amount of cooling performed by said cooling medium circuit, said thermostat being responsive with respect to the temperature of said cooling medium.

6. The apparatus for recording a thermooptical image of claim 4 further comprising an antireflection disk positioned between said thermooptical foil and said digital camera.

7. The apparatus for recording a thermooptical image of claim 4, said thermooptical foil having a relaxed position, said thermooptical foil does not come into contact with said cooling box when in the relaxed position.

8. The apparatus for recording a thermooptical image of claim 4, said frame having a relaxed position and being springingly connected to said casing with at least one mounting device, each said at least one mounting device comprising:

a steel pin extending from said frame to said casing; and

a spring having an unloaded condition and an unloaded length and being inverted over said steel pin, said spring extending from said frame to said casing, wherein said spring assumes said unloaded length when assuming said unloaded condition, said unloaded length of said spring being sufficient to maintain a spacial clearance between said cooling box and said thermooptical foil.

9. The apparatus for recording a thermooptical image of claim 8, compression of each said spring permits said frame to assume a non-relaxed position and further permits contact between said thermooptical foil and said cooling box.

10. The apparatus for recording a thermooptical image of claim 4 further comprising a clamping device having a pad for pressing the breast against said thermooptical foil.

11. The apparatus for recording a thermooptical image of claim 4 further comprising a clamping device for clamping the breast against said thermooptical foil, said clamping device comprising:

a pad for pressing the breast against said thermooptical foil; and

a mounting support for providing support for said pad and for providing pressure for said pad against said breast.

12. The apparatus for recording a thermooptical image of claim 4 further comprising a clamping device comprising:

a pad for pressing the breast against said thermooptical foil; and

a mounting support connected to said casing, said mounting support extending parallel to said frame for providing support for said pad, the spacing between said pad and said thermooptical foil being variable.

13. The apparatus for recording a thermooptical image of claim 4 having a clamping device comprising:

a pad for pressing the breast against said thermooptical foil, said pad having a major planar pressing surface; and

a mounting support having a major horizontal dimension and being connected to said casing, said mounting support providing support for said pad, the spacing between said pad and said thermooptical foil being variable, said major planar pressing surface of said pad positioned at about a right angle to said major horizontal dimension of said mounting support.

14. The apparatus for recording a thermooptical image of claim 4 further comprising:

said frame having a relaxed position, a substantially quadrangular shape, first, second, third and fourth corners, and being springingly connected to said casing with one steel pin in each said corner of said frame, each said steel pin extending from said frame to said casing;

each said steel pin having a spring, each said spring having an unloaded condition and an unloaded length and being inverted over said pin, each said spring extending from said frame to said casing wherein said spring assumes said unloaded length when assuming said unloaded condition, said unloaded length of said spring being sufficient to maintain a spacial clearance between said cooling box and said thermooptical foil.

15. The apparatus for recording a thermooptical image of claim 14, compression of said springs permits said frame to assume a non-relaxed position and further permits contact between said thermooptical foil and said cooling box.

16. The apparatus for recording a thermooptical image of claim 4, said casing being positioned on a multi-articulation arm to permit variable positioning of said casing.

17. The apparatus for recording a thermooptical image of claim 4, said casing being positioned on a multi-articulation arm mounted on an instrument trolley to permit variable positioning of said casing with respect to said instrument trolley.
18. The apparatus for recording a thermooptical image of claim 4 further comprising a monitor screen connected to said digital camera for monitoring images recorded with said digital camera.
19. The apparatus for recording a thermooptical image of claim 4 further comprising a computer for processing images collected with said digital camera.
20. The apparatus for recording a thermooptical image of claim 4 further comprising a computer for operating said apparatus and for processing information collected with said digital camera.
21. The apparatus for recording a thermooptical image of claim 4 further comprising an information storage medium for storing digital images recorded with said digital camera.
22. The apparatus for recording a thermooptical image of claim 4 further comprising printer output device for producing digital images recorded with said digital camera in a printed format.
23. The apparatus for recording a thermooptical image of claim 4 further comprising an image evaluating device connected to said digital camera for automatic evaluation of information contained in images recorded with said digital camera in response to pathological changes.
24. The apparatus for recording a thermooptical image of claim 4 further comprising an image evaluating device connected to said digital camera for comparing information contained in images recorded with said digital camera to reference images.
25. The apparatus for recording a thermooptical image of claim 4 further comprising an image evaluating device connected to said digital camera for comparing an image recorded by said digital camera for structures or features characteristic of mammary carcinomas.
26. The apparatus for recording a thermooptical image of claim 4 further comprising a monitor screen, said monitor screen being subdivided into first and second windows, said first window configured to display

the image recorded by said digital camera, said second image configured to display a reference image for comparison to said first window.

27. An apparatus for recording a thermooptical image of a female breast comprising:

a casing having at least one opaque side and a non-opaque side, said non-opaque side being positioned to face a location for the breast when the image is recorded;

a thermooptical foil for producing a thermooptical image of the breast having at least first and second surfaces and being positioned on a frame located between said casing and the location for the breast, said first surface of said thermooptical foil facing said non-opaque side of said casing, said second surface of said thermooptical foil being positioned to contact the breast;

said frame having a relaxed position, a substantially quadrangular shape, first, second, third and fourth corners, and being springingly connected to said casing with one steel pin in each said corner of said frame, each said steel pin extending from said frame to said casing and having a spring, each said spring having an unloaded condition and an unloaded length and being inverted over said pin, each said spring extending from said frame to said casing wherein said spring assumes said unloaded length when assuming said unloaded condition, said unloaded length of said spring being sufficient to maintain a spacial clearance between said cooling box and said thermooptical foil, compression of said springs permits said frame to assume a non-relaxed position and further permits contact between said thermooptical foil and said cooling box;

a clamping device for clamping the breast against said thermooptical foil, said clamping device having a pad for pressing the breast against said thermooptical foil and a mounting support for providing support for said pad and for providing pressure for said pad against said breast;

a cooling box mounted adjacent said first surface of said thermooptical foil for cooling said thermooptical foil to a standard temperature at a time when said thermooptical foil contacts the breast;

a cooling medium circuit for providing a cooling medium to effect cooling of said cooling box, said cooling medium circuit having a cooling medium inlet for supplying said cooling medium to said cooling box, a cooling medium outlet for removing said cooling medium from said cooling box, and a thermostat for

measuring the amount of cooling performed by said cooling medium circuit, said thermostat being responsive to the temperature of said cooling medium;

a timer for measuring a presettable amount of time that passes after said thermooptical foil begins to be cooled by said cooling box;

an illuminating system for illuminating said thermooptical foil within said casing; and

a digital camera positioned to record the thermooptical image of the breast on said thermooptical foil from within said casing after the presettable amount of time passes; and

an antireflection disk positioned between said thermooptical foil and said digital camera.

28. An apparatus for recording a thermooptical image of a female breast comprising:

a casing having at least one opaque side and a non-opaque side, said non-opaque side being positioned to face a location for the breast when the image is recorded, said casing being positioned on a multi-articulation arm mounted on an instrument trolley to permit variable positioning of said casing with respect to said instrument trolley;

a thermooptical foil for producing a thermooptical image of the breast having at least first and second surfaces and being positioned on a frame located between said casing and the location for the breast, said first surface of said thermooptical foil facing said non-opaque side of said casing, said second surface of said thermooptical foil being positioned to contact the breast;

said frame having a relaxed position, a substantially quadrangular shape, first, second, third and fourth corners, and being springingly connected to said casing with one steel pin in each said corner of said frame, each said steel pin extending from said frame to said casing and having a spring, each said spring having an unloaded condition and an unloaded length and being inverted over said pin, each said spring extending from said frame to said casing wherein said spring assumes said unloaded length when assuming said unloaded condition, said unloaded length of said spring being sufficient to maintain a spacial clearance between said cooling box and said thermooptical foil, compression of said springs permits said frame to assume a non-relaxed position and further permits contact between said thermooptical foil and said cooling box;

a clamping device for clamping the breast against said thermooptical foil, said clamping device having a pad for pressing the breast against said thermooptical foil and a mounting support for providing support for said pad and for providing pressure for said pad against said breast;

a cooling box mounted adjacent said first surface of said thermooptical foil for cooling said thermooptical foil to a standard temperature at a time when said thermooptical foil contacts the breast;

a cooling medium circuit for providing a cooling medium to effect cooling of said cooling box, said cooling medium circuit having a cooling medium inlet for supplying said cooling medium to said cooling box, a cooling medium outlet for removing said cooling medium from said cooling box, and a thermostat for measuring the amount of cooling performed by said cooling medium circuit, said thermostat being responsive to the temperature of said cooling medium;

a timer for measuring a presettable amount of time that passes after said thermooptical foil begins to be cooled by said cooling box;

an illuminating system for illuminating said thermooptical foil within said casing; and

a digital camera positioned to record the thermooptical image of the breast on said thermooptical foil from within said casing after the presettable amount of time passes;

an antireflection disk positioned between said thermooptical foil and said digital camera;

a monitor screen connected to said digital camera for monitoring images recorded with said digital camera; and

a computer for operating said apparatus and for processing information collected with said digital camera.

29. A method of recording a thermooptical image of a female breast on a thermooptical foil comprising: positioning the thermooptical foil against a breast;

cooling the thermooptical foil to a constant temperature for a presettable amount of time while the thermooptical foil is against the breast; and

recording a thermooptical image of the foil against the breast at the end of the presettable amount of time.

30. The method of claim 29 which includes recording the thermooptical image from within a casing which is opaque except for a side facing the thermooptical foil and illuminating the thermooptical foil at the time of recording the thermooptical image.

31. The method of claim 29 in which the thermooptical image recorded is examined for pathological changes in the breast.

32. The method of claim 29 in which the thermooptical image recorded is compared to a previously recorded thermooptical image for comparison and evaluation of pathological changes.

## APPARATUS FOR RECORDING A THERMOOPTICAL IMAGE OF THE FEMALE BREAST

The present invention relates to an apparatus for recording a thermooptical image of the female breast.

For the diagnosis of mammary carcinomas and early detection within the framework of preventative medical examinations, most frequently mammography, i.e. an x-ray method is used. This method leads to a very limited radiation exposure for the patient. As a supplement to mammography thermography is available in which with the aid of the skin temperature mammary carcinomas can be diagnosed on the breast.

The prior art has proposed that most varied methods for this purpose. In one group of methods the skin temperatures are directly measured on the breast and are optionally electronically further processed. Thus, e.g. WO 79/00594 and U.S. Patent 3,970,074 disclose apparatuses in which the breast is pressed against a plate equipped in matrix-like manner with temperature sensors and measurement of the skin temperature takes place. The measured data are electronically processed and specific temperature distributions on the skin are an indication of a mammary carcinoma.

U.S. Patent 4,055,166 discloses a brassier, which is fitted with individual temperature sensors. Thus, the skin temperature is constantly checked at the corresponding points. Specific changes to the skin temperature indicate the existence of mammary carcinomas.

A second group of thermography methods is constituted by so-called plate thermography and a corresponding apparatus is disclosed by D.E. 83 26 341 U1. A thermographic plate is pressed onto the female breast. As a function of the temperature, a thermographic coating of the plate assumes



different colors. This renders optically visible in thermographic manner the pattern of vessels, which are warmer than other areas. Specific structures or features indicate abnormal changes. The actual diagnostic method of plate thermography is described in greater detail in "Atlas der Plattenthermographie" by G. Lauth and G. Mühlberger. This atlas gives an introduction to doctors inexperienced in plate thermography. The performance of plate thermography requires very considerable diagnostic experience on the part of the treating doctor and is subject to a high error rate, particularly in the case of inexperienced doctors.

On the basis of this, the problem of the invention is to provide an apparatus facilitating diagnosis of pathological changes.

According to the invention this problem is solved by an apparatus for recording a thermo optical image of the female breast with a casing which is opaque except on the side facing the breast, where it carries a frame, a thermo optical foil, which can be fixed to the frame, a transparent cooling box arranged on the frame side remote from the breast and having on its side remote from the breast an antireflection disk, which has a cooling medium inlet and a cooling medium outlet and in its initial position is not in contact with the foil, a thermostat adjustable with respect to the temperature of a cooling medium and which for the formation of a cooling circuit is connected by means of hose lines to the cooling medium inlet and outlet, an illuminating system located in the casing for illuminating the thermooptical foil, a digital camera positioned facing the frame in the casing, a clamping device for clamping the breast between two surfaces, one of said two surfaces being formed by the foil, a contact producing device for producing a surface contact between a cooling box side facing the foil and the foil side remote from the breast, a timing system for measuring the time duration as from

producing contact, and a release mechanism connected to the timing system for the automatic release of the digital camera at the end of a presettable time duration.

According to a special embodiment of the invention, the clamping device comprises a pad extending parallel to the frame and connected to the casing and whose spacing from the frame can be modified.

In particular, the pad can be connected to the casing by means of a mounting support located at right angles thereto.

According to another special embodiment of the invention, the frame is quadrangular and at its four corners is held on the casing by means of pins, springs extending concentrically to the pins in such a way that a foil fixed to the frame is at a distance from the cooling box when the springs are in the unloaded state.

A locking device for locking the frame on producing contact between the foil and the cooling box after compressing the springs can be provided.

There can also be a multi-articulation arm, to whose one end is fitted the casing.

Another special embodiment of the invention is characterized by an instrument trolley connected to the other end of the arm and which permits an easy transportation of the apparatus and also an easy handling of the casing in situ.

Advantageously another embodiment of the invention with a screen connected to the digital camera is provided and as a result images can be observed on the screen.

Advantageously there is a computer with a keyboard.

It is in particular possible for the computer to contain the timing system and the release mechanism.

A further special embodiment of the invention is characterized by a storage means for storing the digital images recorded by means of the digital camera.

Another special embodiment of the invention is characterized by an output device for outputting the digital images on a printer or a storage medium. The storage medium can e.g. be a CD-ROM or a diskette.

Another special embodiment of the invention is characterized by an image evaluating device connected to the digital camera for the automatic evaluation of the information contained in the recorded image in connection with the existence of a pathological change.

Advantageously the image evaluating device has a means for comparing the present image with earlier images of the same breast or with reference images.

The image evaluating device can also have a means for examining an image for structures or features characteristic of a mammary carcinoma.

Finally, another embodiment of the invention is characterized in that the screen is subdivided into two parts, one window being used for displaying the present image and the other window for displaying an earlier image of the same breast or a reference image.

The invention is based on the surprising finding that through the cooling box combined with the cooling circuit, the illuminating system and the clamping device it is possible to standardize thermooptical images. This means that for the same patient the same recording conditions can always be reproduced, so that the treating doctor can easily detect pathological changes, i.e. can more easily make a more reliable diagnosis. In addition, standardized, thermooptical images permit an automatic diagnosis.

Further features and advantages of the invention can be gathered from the claims and the following description of an embodiment with reference to the attached drawings, wherein show:

FIG. 1 is a diagrammatic side view of part of a special embodiment of an apparatus for recording a thermooptical image of the female breast.

FIG. 2 is another part of the apparatus of FIG. 1.

FIG. 3 is diagrammatically the complete apparatus of FIG. 1 when used on a patient.

FIG. 1 diagrammatically shows part of a special embodiment of the apparatus according to the invention in side view. The apparatus comprises a casing 4 which, for standardizing the thermooptical images, is opaque except on the side facing the breast where it has a frame 9. This is a prerequisite for recording free from external reflections. The frame 9 receives a thermooptical foil or film 1. On the side of the frame 9 directed towards the casing interior is provided a transparent cooling box or cooler 7 with an antireflection disk 6 placed on its side directed towards the casing interior. The antireflection disk 6 simultaneously forms the rear wall of the cooling box 7. The foil 1 stretched over the narrow frame 9 is at a distance of 2 to 3 centimeters in front of the front wall 8 of the cooling box 7. The quadrangular frame 9 is held in the four corners of the casing 4 by steel pins 10 and the spacing of the foil 1 from the front wall of the cooling box 7 is ensured by four springs 11. The springs 11 are inverted over the pins 10 and in the relaxed state are sufficiently long to hold the foil 1 at the said spacing from the front wall 8 of the cooling box 7. After placing the foil 1 on the breast to be examined, it is possible to correct the position of said foil 1 without any surface contact having taken place between the foil 1 and the front wall 8 of the cooling box 7.

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The cooling box 7 has a cooling medium inlet 12a and a cooling medium outlet 12b connecting it in a circuit with a thermostat 17 by means of hose lines 12c (cf. fig. 2). Water is the cooling medium. A continuous water circulation and a constant water temperature ensure the constancy of the temperature of the foil 1. Based on the thermal sensitivity of the foil 1, the set cooling should always be constant. It is possible to manually adjust the degree of cooling by means of a keyboard 13 (cf. fig. 2) of a computer 3 (cf. fig. 2).

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The casing 4 also contains a digital camera 2 facing the frame 9. An illuminating system in the form of two lamps 5 is used for illuminating the foil 1 and is oriented in such a way that recordings using the digital camera are optimized. The lamps 5 also contribute to standardization.

For the gentle clamping of the breast between the foil 1 and the pad 14, the latter can be moved backwards and forwards in the horizontal plane by means of a mounting support 15 in FIG. 1 and this also contributes to standardization.

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FIG. 2 diagrammatically shows another part of the apparatus of FIG. 1. A thermostat 17, a computer 3 with a keyboard 13 and a screen 16 are located in an instrument trolley 19, to which is fixed a not shown, but visible in FIG. 3 multi-articulation arm 18, to whose other end is fixed the casing 4. The arm permits mobility and can be locked. In its interior are located the not shown supply lines for the digital camera 2, the cooling of the cooling box 7 and the illuminating systems 5. The use of the system will now be described relative to FIG. 3, in which the foil 1 is rotated forwards by approximately 90° for representation purposes.

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By placing a thermoplastic foil 1 on the female breast a heat pattern in different colors corresponding to the areal thermal states of the skin appears on the foil. This thermal pattern is reversible after the foil has been removed from the breast. Coloring on the foil 1 can be minimized

by supplying cold. The color patterns are more sharply contoured and more contrasty to the black environment. Through the supply of cold the main aim is to "cool away" the skin heat and the peaks of heat dissipated from more low-lying heat sources are displayed.

Recording positions correspond to those for mammography, but with the difference that in the case of mammae of the of the normal size, two lateral and two craniocaudal exposures are made for each breast. This is due to the fact that in "vascugraphy" the emitted heat is measured and a greater sensitivity can be obtained by measuring from both sides. After placing the foil 1 on the breast, the latter is held with the soft pad 14, which can be brought into position by the patient. This has the advantage of avoiding the unpleasant association with the "squeezing examination" of mammography. As in the case of a constant temperature of the cooling medium and constant heat sensitivity of the foil during the examination the duration of cooling is not without significance and at the same time standardization is required, it is necessary to define the starting and ending time of the cooling process. This is brought about in that at the instant when the foil 1 is gently pressed counter to the tension of springs 10 on a cooling box 7 and a not shown locking means snaps in, a not shown timing system starts to measure the cooling time period and at the end of a presettable period automatic release of the digital camera 2 takes place by means of a not shown release mechanism. After each shot or recording, the pad 14 is brought into its starting or initial position by means of a mounting support 15 with not shown gas spring pressure. Through standardizing these settings a maximum reproducibility is achieved. During recording or shooting, all the settings can be monitored on the screen 16. The dimensions of the foil correspond to those of a mammographic film with the size 18 x 24 centimeters. On replacing the foil by a finished mammography image (e.g. a positive case) and homogeneous transillumination of the film from the outside in the direction of the

digital camera 2, it is possible to obtain a simple, inexpensive form of digitized storage of the mammogram of the particular patient. The congruent superimposing of the thermal image and the mammogram on the screen can provide valuable information to the diagnosing doctor.

5 The thermooptical image recorded by the digital camera 2 is transferred to the computer 3, where an image evaluating means carries out an automatic evaluation of the image by means of a special software.

10 By means of the apparatus described hereinbefore the interpretation of thermooptical images is no longer left to the examining doctor and is instead carried out by an image evaluating means. As a result of the thermographically obtained vascular pattern and the shape of the patient's vessels with the aid of reference data, said means detects pathological changes. This is particularly appropriate during the initial examinations of a patient. However, if previous recordings or exposures exist, it is possible to carry out a comparison of the present recording with the previous one. This procedure is based on the finding that the vascular pattern in the female breast, in the same way as a fingerprint, is individual to every woman and remains unchanged. If changes occur in the vascular pattern and therefore in the thermooptical image, this indicates a pathological change, which can then be further investigated, e.g. by a biopsy.

The features of the invention disclosed in the preceding description, the drawings and the claims can be essential to the implementation of the different embodiments of the invention, both individually and in random combination.

## Claims

1. Apparatus for recording a thermooptical image of the female breast having:
- a casing (4), which is opaque except for side facing the breast, where it carries a frame (9),
  - a thermooptical foil (1), which is fixable to the frame (9), a transparent cooling box (7)
  - located on the side of the frame (9) remote from the breast and having an antireflection disk (6)
  - located on its side remote from the breast and which is provided with a cooling medium inlet (12a)
  - and a cooling medium outlet (12b) and in its starting position is not in contact with the foil (1),
  - a thermostat (17) adjustable with respect to the temperature of a cooling medium and which
  - for the formation of a cooling circuit is connected by means of hose lines (12c) to the cooling medium
  - inlet (12a) and outlet 12(b),
  - an illuminating system for illuminating the thermooptical film (1) located in the casing (4),
  - a digital camera (2) positioned facing the frame (9) in the casing (4),
  - a clamping device for clamping the breast between two surfaces, one of the two surfaces being
  - formed by the foil (1),
  - a contact producing device for producing a surface contact between a side of the cooling box
  - (7) facing the foil (1) and the side of the foil (1) remote from the breast,
  - a timing system for measuring the time period as from the producing of contact and
  - a release mechanism connected to the timing system for the automatic release of the digital
  - camera (2) at the end of a presettable time period.



2. Apparatus according to claim 1, characterized in that the clamping device comprises a pad (14) connected to the casing (4) and extending parallel to the frame (9) and whose spacing from the latter is variable.

5 3. Apparatus according to claim 2, characterized in that the pad (14) is connected to the casing (4) by means of a mounting support (15) arranged at right angles thereto.

10 4. Apparatus according to claim 1, characterized in that the frame (9) is quadrangular and is held on the casing (4) at its four corners by means of pins (10), springs (11) extending concentrically to the pins (10) in such a way that a foil (1) fixed to the frame (9) in an unloaded state of the springs (11) is at a distance from the cooling box (7).

15 5. Apparatus according to claim 4, characterized by a locking device for locking the frame (9) on producing contact between the foil (1) and the cooling box (7) after compressing the springs (11).

6. Apparatus according to claim 1, characterized by a multi-articulation arm, to whose one end is fitted the casing (4).

20 7. Apparatus according to claim 6, characterized by an instrument trolley (19) connected to the other end of the arm (18).

8. Apparatus according to claim 1, characterized by a screen (16) connected to the digital camera (2).

9. Apparatus according to claim 1, characterized by a computer (3) with a keyboard (13).

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10. Apparatus according to claim 9, characterized in that the computer (3) contains the timing system and the release mechanism.

11. Apparatus according to claim 1, characterized by a storage means for storing the digital images recorded by means of the digital camera (2).

12. Apparatus according to claim 1, characterized by an output device for outputting the digital images on a printer or a storage medium.

13. Apparatus according to claim 1, characterized by an image evaluating device connected to the digital camera (2) for the automatic evaluation of the information contained in the recorded image with respect to the existence of a pathological change.

14. Apparatus according to claim 13, characterized in that the image evaluating device has a means for comparing the present image with earlier images of the same breast or with reference images.

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Fig. 1

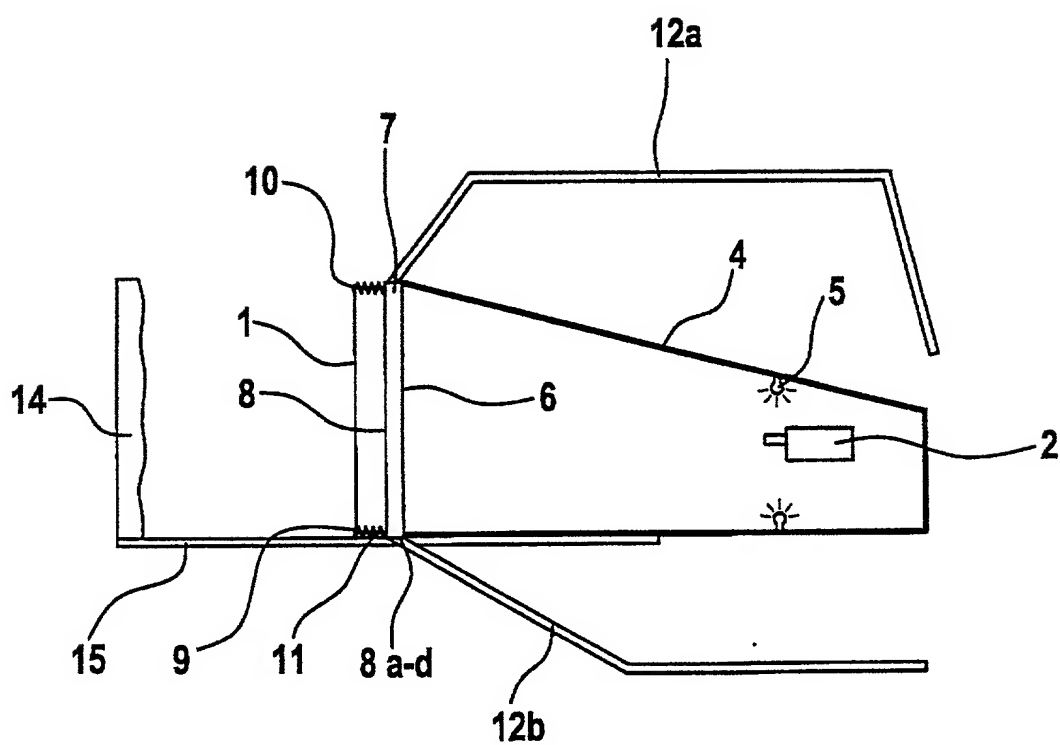
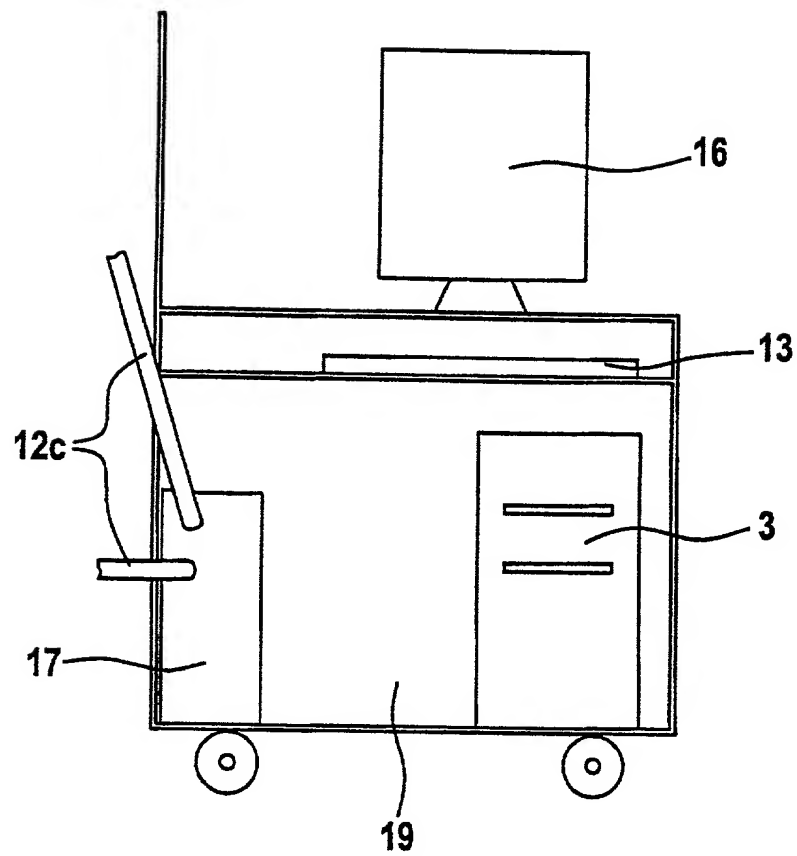


Fig. 2



3/3

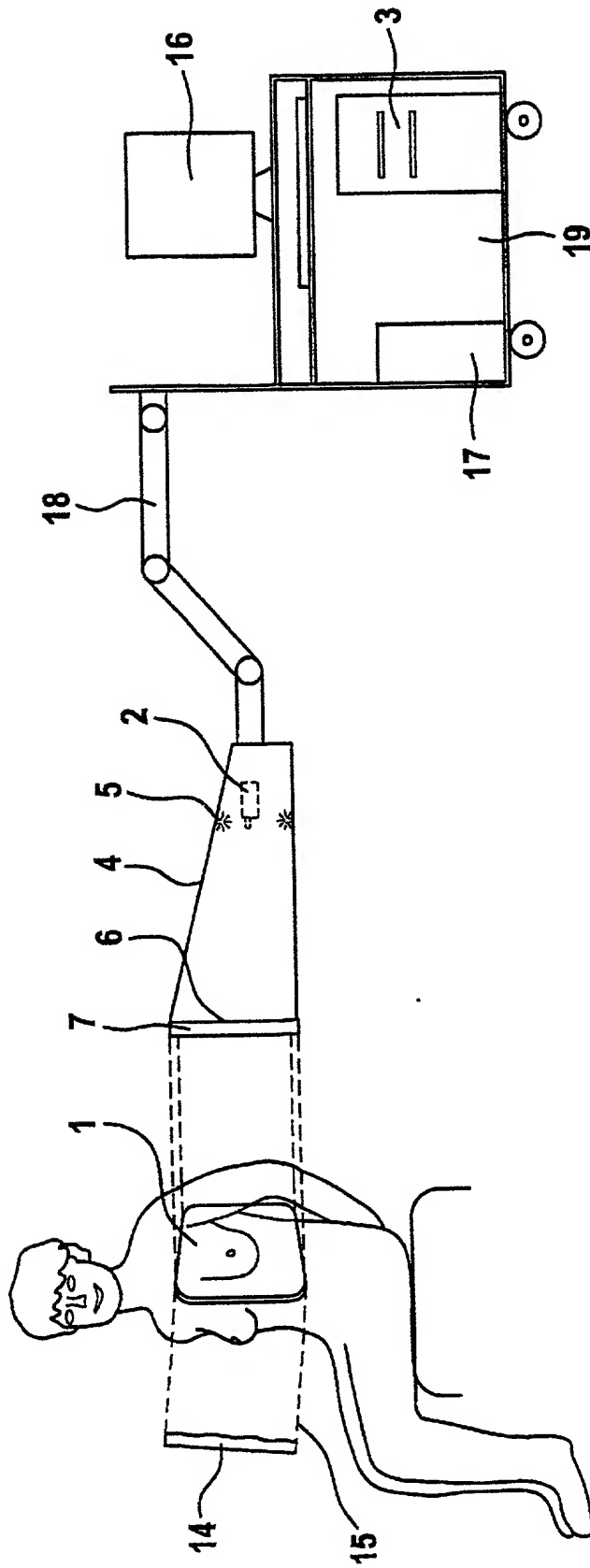
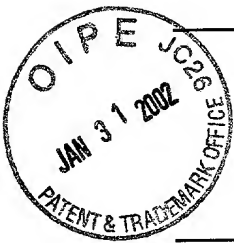


Fig. 3

**COMBINED DECLARATION AND POWER OF ATTORNEY**

(ORIGINAL, DESIGN, NATIONAL STAGE OF PCT, SUPPLEMENTAL, DIVISIONAL, CONTINUATION, OR C-I-P)

As a below named inventor, I hereby declare that:

**TYPE OF DECLARATION**

This declaration is of the following type:

(check one applicable item below)

- ☐ original.  
☐ design.  
☐ supplemental.

**NOTE:** If the declaration is for an International Application being filed as a divisional, continuation or continuation-in-part application, do not check next item; check appropriate one of last three items.

- ☒ national stage of PCT.

**NOTE:** If one of the following 3 items apply, then complete and also attach ADDED PAGES FOR DIVISIONAL, CONTINUATION OR C-I-P.

**NOTE:** See 37 C.F.R. § 1.63(d) (continued prosecution application) for use of a prior nonprovisional application declaration in the continuation or divisional application being filed on behalf of the same or fewer of the inventors named in the prior application.

- ☐ divisional.  
☐ continuation.

**NOTE:** Where an application discloses and claims subject matter not disclosed in the prior application, or a continuation or divisional application names an inventor not named in the prior application, a continuation-in-part application must be filed under 37 C.F.R. § 1.53(b) (application filing requirements - nonprovisional application).

- ☐ continuation-in-part (C-I-P).

**INVENTORSHIP IDENTIFICATION**

**WARNING:** If the inventors are each not the inventors of all the claims, an explanation of the facts, including the ownership of all the claims at the time the last claimed invention was made, should be submitted.

My residence, post office address and citizenship are as stated below, next to my name. I believe that I am the original, first and sole inventor (if only one name is listed below) or an original, first and joint inventor (if plural names are listed below) of the subject matter that is claimed, and for which a patent is sought on the invention entitled:

**TITLE OF INVENTION**

**Apparatus for Recording a Thermo-optical Image of the Female Breast**

## SPECIFICATION IDENTIFICATION

the specification of which:

(complete (a), (b), or (c))

(a) ☐ is attached hereto.

NOTE: "The following combinations of information supplied in an oath or declaration filed on the application filing date with a specification are acceptable as minimums for identifying a specification and compliance with any one of the items below will be accepted as complying with the identification requirement of 37 C.F.R. § 1.63:

"(1) name of inventor(s) and reference to an attached specification which is both attached to the oath or declaration at the time of execution and submitted with the oath or declaration on filing;

"(2) name of inventor(s), and attorney docket number which was on the specification as filed; or

"(3) name of inventor(s), and title which was on the specification as filed."

Notice of July 13, 1995 (1177 O.G. 60).

(b) ☒ was filed on October 22, 2001, as ☒ Serial No. 10/018,131  
or ☐ \_\_\_\_\_  
and was amended on \_\_\_\_\_ (if applicable).

NOTE: Amendments filed after the original papers are deposited with the PTO that contain new matter are not accorded a filing date by being referred to in the declaration. Accordingly, the amendments involved are those filed with the application papers or, in the case of a supplemental declaration, are those amendments claiming matter not encompassed in the original statement of invention or claims. See 37 C.F.R. § 1.67.

NOTE: "The following combinations of information supplied in an oath or declaration filed after the filing date are acceptable as minimums for identifying a specification and compliance with any one of the items below will be acceptable as complying with the identification requirement of 37 C.F.R. § 1.63:

"(1) name of inventor(s) and application number (consisting of the series code and the serial number; e.g. 08/123,456);

"(2) name of inventor(s), serial number and filing date;

"(3) name of inventor(s) and attorney docket number which was on the specification as filed;

"(4) name of inventor(s), title which was on the specification as filed and filing date;

"(5) name of inventor(s), title which was on the specification as filed and reference to an attached specification which is both attached to the oath or declaration at the time of execution and submitted with the oath or declaration; or

"(6) name of inventor(s), title which was on the specification as filed and accompanied by a cover letter accurately identifying the application for which it was intended by either the application number (consisting of the series code and the serial number: e.g., 08/123,456), or serial number and filing date. Absent any statement(s) to the contrary, it will be presumed that the application filed in the PTO is the application which the inventor(s) executed by signing the oath or declaration."

Notice of July 13, 1995 (1177 O.G. 60), M.P.E.P. § 601.01(a), 6<sup>th</sup> ed., rev. 3.

(c) ☐ was described and claimed in PCT International Application No. \_\_\_\_\_  
filed on \_\_\_\_\_ and as amended under PCT Article 19 on  
\_\_\_\_\_ (if any).



**SUPPLEMENTAL DECLARATION (37 C.F.R. § 1.67(b))**

(complete the following where a supplemental declaration is being submitted)

- ☐ I hereby declare that the subject matter of the
- ☐ attached amendment
  - ☐ amendment filed on \_\_\_\_\_

was part of my/our invention and was invented before the filing date of the original application, above-identified, for such invention.

**ACKNOWLEDGMENT OF REVIEW OF PAPERS AND DUTY OF CANDOR**

I hereby state that I have reviewed and understand the contents of the above-identified specification, including the claims, as amended by any amendment referred to above.

I acknowledge the duty to disclose information, which is material to patentability as defined in 37, Code of Federal Regulations § 1.56,

*(also check the following items, if desired)*

- ☒ and which is material to the examination of this application, namely, information where there is a substantial likelihood that a reasonable Examiner would consider it important in deciding whether to allow the application to issue as a patent, and
- ☐ in compliance with this duty, there is attached an information disclosure statement, in accordance with 37 C.F.R. § 1.98.

**PRIORITY CLAIM (35 U.S.C. §§ 119(a)-(d))**

**NOTE:** *"The claim to priority need be in no special form and may be made by the attorney or agent if the foreign application is referred to in the oath or declaration as required by § 1.63. The claim for priority and the certified copy of the foreign application specified in 35 U.S.C. § 119(b) must be filed in the case of an interference (§ 1.630), when necessary to overcome the date of a reference relied upon by the examiner, when specifically required by the examiner, and in all other situations, before the patent is granted. If the claim for priority or the certified copy of the foreign application is filed after the date the issue fee is paid, it must be accompanied by a petition requesting entry and by the fee set forth in § 1.17(i). If the certified copy is not in the English language, a translation need not be filed except in the case of interference; or when necessary to overcome the date of a reference relied upon by the examiner; or when specifically required by the examiner, in which event an English language translation must be filed together with a statement that the translation of the certified copy is accurate." 37 C.F.R. § 1.55(a).*

I hereby claim foreign priority benefits under Title 35, United States Code, § 119(a)-(d) of any foreign application(s) for patent or inventor's certificate or of any PCT International application(s) designating at least one country other than the United States of America listed below and have also identified below any foreign application(s) for patent or inventor's certificate or any PCT international application(s) designating at least one country other than the United States of America filed by me on the same subject matter having a filing date before that of the application(s) of which priority is claimed.

(complete (d) or (e))

- (d) ☐ no such applications have been filed.
- (e) ☒ such applications have been filed as follows.

**NOTE:** *Where item (c) is entered above and the International Application which designed the U.S. itself claimed priority check item (e), enter the details below and make the priority claim.*

**PRIOR FOREIGN/PCT APPLICATION(S) FILED WITHIN 12 MONTHS  
(6 MONTHS FOR DESIGN) PRIOR TO THIS APPLICATION  
AND ANY PRIORITY CLAIMS UNDER 35 U.S.C. § 119(a)-(d)**

COUNTRY (OR INDICATE IF PCT)	APPLICATION NUMBER	DATE OF FILING (day, month, year)	PRIORITY CLAIMS UNDER 37 USC 119	
			<input type="checkbox"/> Yes	No <input type="checkbox"/>
			<input type="checkbox"/> Yes	No <input type="checkbox"/>
			<input type="checkbox"/> Yes	No <input type="checkbox"/>
			<input type="checkbox"/> Yes	No <input type="checkbox"/>
			<input type="checkbox"/> Yes	No <input type="checkbox"/>

**CLAIM FOR BENEFIT OF PRIOR U.S. PROVISIONAL APPLICATION(S)  
(34 U.S.C. § 119(e))**

I hereby claim the benefit under Title 35, United States Code, § 119(e) of any United States provisional application(s) listed below:

PROVISIONAL APPLICATION NUMBER

FILING DATE

\_\_\_\_\_/\_\_\_\_\_  
\_\_\_\_\_/\_\_\_\_\_  
\_\_\_\_\_/\_\_\_\_\_

\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

**CLAIM FOR BENEFIT OF EARLIER US/PCT APPLICATION(S)  
UNDER 35 U.S.C. § 120**

- ☒ The claim for the benefit of any such applications are set forth in the attached ADDED PAGES TO COMBINED DECLARATION AND POWER OF ATTORNEY FOR DIVISIONAL, CONTINUATION OR CONTINUATION-IN-PART (C-I-P) APPLICATION.

ALL FOREIGN APPLICATION(S), IF ANY, FILED MORE THAN 12 MONTHS  
(6 MONTHS FOR DESIGN) PRIOR TO THIS U.S. APPLICATION

DS29907186.3 - filed 4/22/99

DS19927426.6 - filed 6/16/99

NOTE: If the application filed more than 12 months from the filing date of this application is a PCT filing forming the basis for this application entering the United States as (1) the national stage, or (2) a continuation, divisional, or continuation-in-part, then also complete ADDED PAGES TO COMBINED DECLARATION AND POWER OF ATTORNEY FOR DIVISIONAL, CONTINUATION OR C-I-P APPLICATION for benefit of the prior U.S. or PCT application(s) under 35 U.S.C. § 120.

POWER OF ATTORNEY

I hereby appoint the following practitioner(s) to prosecute this application and transact all business in the Patent and Trademark Office connected therewith.

(list name and registration number)

2

Jon L. Woodard 45,515  
Edward W. Goebel, Jr. 22,678

(check the following item, if applicable)

- ☒ I hereby appoint the practitioner(s) associated with the Customer Number provided below to prosecute this application and to transact all business in the Patent and Trademark office connected therewith.
- ☐ Attached, as part of this declaration and power of attorney, is the authorization of the above-named practitioner(s) to accept and follow instructions from my representative(s).

SEND CORRESPONDENCE TO:

- ☒ Jon L Woodard  
Edward W. Goebel, Jr., Esq.  
MacDonald, Illig, Jones & Britton LLP  
100 State Street  
Suite 700  
Erie, PA 16507-1498

DIRECT TELEPHONE CALLS TO:

(Name and telephone number)

814-870-7664  
814-870-7706

- ☐ Customer Number \_\_\_\_\_

## DECLARATION

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

### SIGNATURE(S)

NOTE: Carefully indicate the family (or last) name, as it should appear on the filing receipt and all other documents.

NOTE: Each inventor must be identified by full name, including the family name, and at least one given name without abbreviation together with any other given name or initial, and by his/her residence, post office address and country of citizenship. 37 C.F.R. § 1.63(a)(3).

NOTE: Inventors may execute separate declarations/oaths provided each declaration/oath sets forth all the inventors. Section 1.63(a)(3) requires that a declaration/oath, *inter alia*, identify each inventor and prohibits the execution of separate declarations/oaths which each sets forth only the name of the executing inventor. 62 Fed. Reg. 53,131, 53, 142, October 10, 1997.

#### Full name of sole or first inventor

Heinrich

(GIVEN NAME)

(MIDDLE INITIAL OR NAME)

Wehberg

FAMILY (OR LAST NAME)

Inventor's signature

Date

1.11.01

Country of Citizenship

Germany

Residence

Etelserstraße 32, 27299 Langwedel, Germany

DEX

Post Office Address

#### Full name of second joint inventor, if any

(GIVEN NAME)

(MIDDLE INITIAL OR NAME)

FAMILY (OR LAST NAME)

Inventor's signature

Date

Country of Citizenship

Residence

Post Office Address

#### Full name of third joint inventor, if any

(GIVEN NAME)

(MIDDLE INITIAL OR NAME)

FAMILY (OR LAST NAME)

Inventor's signature

Date

Country of Citizenship

Residence

Post Office Address

(check proper box(es) for any of the following added page(s)  
that form a part of this declaration

- ☐ **Signature** for fourth and subsequent joint inventors. *Number of pages added*

\_\_\_\_\_.

\* \* \*

- ☐ **Signature** by administrator(trix), executor(trix) or legal representative for deceased or incapacitated inventor. *Number of pages added* \_\_\_\_\_.

\* \* \*

- ☐ **Signature** for inventor who refuses to sign or cannot be reached by person authorized under (37 C.F.R. § 1.47). *Number of pages added* \_\_\_\_\_.

\* \* \*

- ☐ Added page for **signature** by one joint inventor on behalf of deceased inventor(s) where legal representative cannot be appointed in time. (37 C.F.R. § 1.47).

\* \* \*

- ☒ Added pages to combined declaration and power of attorney for divisional, continuation, or continuation-in-part (C-I-P) application. ☐ Number of pages added   3

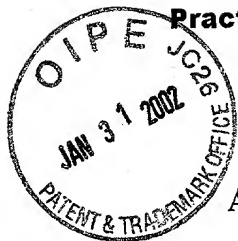
\* \* \*

- ☐ Authorization of practitioner(s) to accept and follow instructions from representative.

\* \* \*

(If no further pages form a part of this Declaration,  
then end this Declaration with this page and check the following item)

- ☐ This declaration ends with this page.



**ADDED PAGE TO COMBINED DECLARATION  
AND POWER OF ATTORNEY FOR DIVISIONAL, CONTINUATION  
OR C-I-P APPLICATION**

(complete this part only if this is a divisional, continuation or C-I-P application)

**CLAIM FOR BENEFIT OF EARLIER U.S./PCT APPLICATION(S)  
UNDER 35 U.S.C. 120**

I hereby claim the benefit, under Title 35, United States Code, § 120, of any United States application(s) or PCT International application(s) designating the United States of America that is/are listed below and, insofar as the subject matter of each of the claims of this application is not disclosed in that/those prior application(s) in the manner provided by the first paragraph of Title 35, United States Code, § 112, I acknowledge the duty to disclose information

- ☒ that is material to patentability as defined in 37, Code of Federal Regulations, § 1.56

*(also check the following item, if desired)*

- ☐ and that is material to the examination of this application, namely, information where there is a substantial likelihood that a reasonable examiner would consider it important in deciding whether to allow the application to issue as a patent,

that occurred between the filing date of the prior application(s) and the national or PCT international filing date of this application. (37 C.F.R. § 1.63(e)).

*(also check the following item, if desired)*

- ☒ In compliance with this duty, there is attached an information disclosure statement, in accordance with 37 C.F.R. § 1.98.

PRIOR U.S. APPLICATIONS OR PCT INTERNATIONAL APPLICATIONS DESIGNATING THE U.S. FOR BENEFIT UNDER 35 USC 120:				
U. S. APPLICATIONS		Status (check one)		
U.S. APPLICATIONS	U.S. FILING DATE	Patented	Pending	Abandoned
1.0 /				
2.0 /				
3.0 /				
PCT APPLICATIONS DESIGNATING THE U.S.				
PCT APPLICATION NO.	PCT FILING DATE	U.S. APPLICATION NOS. ASSIGNED (if any)		
4. PCT/DE00/01243	22 April 1999	0 /		
5.		0 /		
6.		0 /		

**35 USC § 119 PRIORITY CLAIM, IF ANY,  
FOR ABOVE LISTED U.S./PCT APPLICATIONS**

<b>ABOVE APPLICATION NO.</b>	<b>DETAILS OF U.S. PROVISIONAL OR FOREIGN APPLICATION FROM WHICH PRIORITY CLAIMED UNDER 35 USC § 119</b>		
<b>Please indicate appropriate PCT application no.</b>	<b>Country and Application No.</b>	<b>Date of filing (day, month, year)</b>	<b>Date of Issue (day, month, year)</b>
1.			
2.			
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